THE PLANET

Original Article

Evaluation of safety and efficacy of tapinarof in the management of Psoriasis

Mohammad Habibur Rahman[1*], Abu Sayed Mohammad Mostafa[2], Mohammad Kabir[3], S M Hasinur Rahman[4]

ARTICLE INFO

Received: 11 October 2026
Accepted: 20 October 2026
Published Online: 03 November 2026

DOI: 10.5281/zenodo.23911992

Volume: 10, Number: 3, Page: 1075-1078

e-ISSN: 2789-5912
ISSN: 2617-0817

*Corresponding author

ABSTRACT

Background: Psoriasis is a chronic inflammatory disease that can impair quality of life. Tapinarof is a non-steroidal topical aryl hydrocarbon receptor modulator with proven efficacy in plaque psoriasis. However, evidence from Bangladesh is limited. This study evaluated the efficacy and safety of topical tapinarof in patients with psoriasis. **Methods:** This prospective interventional study included 105 patients with psoriasis treated with topical tapinarof for 12 weeks at 250 beded General Hospital, Chandpur, Bangladesh. Disease severity was assessed using PASI, BSA, PGA, and pruritus scores at baseline and weeks 4, 8, and 12, while PASI50, PASI75, PASI90, and adverse events were recorded. Data were analyzed using SPSS version 26.0, with $p<0.05$ considered significant. Ethical approval and informed consent were obtained**. Results:** Among 105 patients, 60.0% were male and 63.8% had moderate psoriasis. At week 12, PASI, BSA, PGA, and pruritus scores significantly improved (all $p<0.001$). PASI50, PASI75, and PASI90 were achieved by 63.8%, 28.6%, and 14.3%, respectively. PASI75 was significantly higher in mild disease (55.6%) than moderate (26.9%) or severe disease (10.0%; $p<0.001$). Most patients (65.7%) reported no adverse events. **Conclusion:** Topical tapinarof demonstrated significant improvement in psoriasis severity over 12 weeks and was generally well tolerated. The findings support its potential as an effective non-steroidal topical treatment for psoriasis.

Keywords: *Psoriasis; Tapinarof; Aryl hydrocarbon receptor; PASI; Topical therapy; Efficacy; Safety; Adverse events.*

1. *Assistant Professor, Department of Skin & VD, Chandpur Medical College, Chandpur, Bangladesh (ORCID: 0009-0005-8386-6153)*
2. *Assistant Professor, Department of Skin & VD, Chandpur Medical College, Chandpur, Bangladesh (ORCID: 0009-0004-6450-9604)*
3. *Assistant Professor, Department of Pediatrics, Chandpur Medical College, Chandpur, Bangladesh (ORCID: 0009-0009-9031-6482)*
4. *Assistant Professor, Department of Skin & VD, Dhaka Medical College, Dhaka, Bangladesh (ORCID: 0009-0009-6311-5343)*

INTRODUCTION

Psoriasis is a chronic immune-mediated inflammatory disease characterized by erythematous, scaly plaques and recurrent disease activity that can impair quality of life. Despite available treatments, long-term control remains challenging due to adverse effects, treatment burden, and poor adherence, highlighting the need for effective and well-tolerated topical therapies [1,2].

Tapinarof is a first-in-class, non-steroidal, topical aryl hydrocarbon receptor (AhR) modulator developed for the treatment of plaque psoriasis. Activation of AhR through the use of tapinarof has been shown to impact multiple immunologic and epidermal pathways, offering an alternative mechanism of action to conventional topical treatments for psoriasis such as corticosteroids and vitamin D analogues [1,3].Tapinarof demonstrated the ability to decrease skin inflammation and dysregulated epidermal barrier function without the unwanted side effects of topical steroids[1,4].

Phase 2 and 3 trials demonstrated significant improvements in plaque psoriasis with once-daily tapinarof cream, supporting the efficacy of the 1% formulation compared with vehicle [5-9]. Long-term studies showed sustained efficacy and favorable tolerability over 52 weeks [4,5]. Japanese phase 3 trials further confirmed clinically meaningful improvements with generally good tolerability [5]. Reviews have also highlighted tapinarof as a steroid-free option for both induction and maintenance therapy [8,10].

However, evidence on the real-world effectiveness and safety of tapinarof in Bangladeshi patients with psoriasis remains limited. Differences in patient characteristics, disease severity, treatment access, adherence, and treatment practices may influence its outcomes. Therefore, local evidence is needed to assess its effectiveness and safety and determine the applicability of international clinical trial findings in Bangladesh. This study aims to assess the effectiveness and safety of topical treatment with tapinarof in patients with psoriasis who presented at the dermatology outpatient clinic. Particular emphasis will be placed on determining the change in disease severity throughout treatment and the incidence of treatment-related adverse events in patients who received topical treatment with tapinarof.

METHODS & MATERIALS

Study design and setting: The prospective interventional study was carried out in the Department of Dermatology and Venereology, 250 beded General Hospital, Chandpur, Bangladesh. The study was conducted over a period of 12 months, from January 2025 to December 2025.

Study population and sample size: A total of 105 patients with psoriasis participated and fulfilled the inclusion criteria. The patients attended at the dermatology outpatient department and were enrolled into the study as per the inclusion and exclusion criteria. The patients were clinically assessed at baseline and followed up at weeks 4, 8, and 12 during treatment.

Selection Criteria:

Inclusion criteria: The patients were eligible for enrollment into the study if they had clinically diagnosed psoriasis, were at least 18 years old at the time of enrollment, had mild to severe disease as defined by the Physician Global Assessment (PGA), were willing to receive topical tapinarof for a duration of 12 weeks, agreed to come for scheduled follow-up visits, and gave written informed consent.

Exclusion criteria: The patients were excluded from the study if they had a known hypersensitivity to tapinarof or any of its ingredients, had received systemic antipsoriatic therapy or phototherapy within the predefined washout period, had an active skin infection or other significant dermatological condition that could interfere with assessments, were taking medicines that could influence the severity of psoriasis, were pregnant or breastfeeding, or were unwilling or incapable of attending scheduled follow-up visits.

Study procedure: The eligible patients were prescribed topical tapinarof as per the study treatment protocol for a period of 12 weeks. A structured data collection sheet was used to collect baseline demographic and clinical information. The data collected comprised of age, sex, duration of psoriasis, family history of psoriasis, history of previous treatment, manifestation, site of involvement, and baseline disease severity.

BDJOURNALS.ORG Copyright © 2026 The Planet. Published by Sher-E-Bangla Medical College, Barishal, Bangladesh. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/).

The severity of the disease was assessed using the Physician Global Assessment (PGA). The Psoriasis Area and Severity Index (PASI), body surface area (BSA), PGA score, and pruritus score were also recorded at baseline, and at weeks 4, 8, and 12.

Assessment of treatment efficacy: The treatment efficacy was assessed by change from baseline in PASI, BSA, PGA, and pruritus score at weeks 4, 8, and 12. The proportions of patients who achieved at least 50%, 75%, and 90% improvement in PASI from baseline were recorded as PASI50, PASI75, and PASI90, respectively. The association between baseline disease severity and PASI75 at week 12, achievement of PASI75 at week 12, was also evaluated.

Safety assessment: The safety of the study drug was assessed throughout the treatment period by recording any adverse events that may occur. The adverse events reported by the participants or observed during clinical surveillance were recorded. Erythema, pruritus, burning or stinging, folliculitis, dryness or scaling, and other treatment-emergent events were documented and summarized in terms of their frequency.

Statistical analysis: All the data generated were entered, cleaned and analyzed using the IBM SPSS Statistics version 26.0 software. Descriptive statistics were used to describe categorical variables as frequencies and percentages. Continuous variables were described using the mean ± standard deviation. An appropriate statistical test for repeated measures was used to analyze the changes in PASI, BSA, PGA, and pruritus score from baseline to week 12. The association between baseline disease severity and achievement of PASI75 at week 12, was examined using the chi-square test or Fisher's exact test, as appropriate. A p-value of <0.05 was considered statistically significant.

Ethical considerations: The study followed the principles of the declaration of Helsinki and was approved by the appropriate ethical review committee at the 250 beded General Hospital,Chandpur. Informed consent was obtained from each study participant and the confidentiality of information provided by the participants was maintained in accordance with the declaration of Helsinki.

RESULTS

Table I presents the sociodemographic and baseline characteristics of the 105 study participants. The largest proportion of the sample was aged between 31 and 40 years (32.4%), followed by the those aged between 41 - 50 years (26.7%), 18-30 years (23.8%), and over 50 years (17.1%). Sixty percent of the study participants were male, while 40% were female. The mean duration of psoriasis was 6.2±4.7 years. Additionally, 25.7% of the study participants reported a family history of psoriasis, while 58.1% had a history of treatment for psoriasis.

Table I
Sociodemographic and baseline characteristics of study participants (*n*=105).

Characteristics	n (%) / Mean ± SD
Age group (years)	
18–30	25 (23.8)
31–40	34 (32.4)
41–50	28 (26.7)
>50	18 (17.1)
Sex	
Male	63 (60.0)
Female	42 (40.0)
The mean duration of psoriasis (years)	6.2 ± 4.7
Family history of psoriasis	27 (25.7)
Previous treatment for psoriasis	61 (58.1)

Table II provides the clinical presentations of psoriasis, including the affected body areas and disease severity in 105 patients. The most common symptoms were scaling (86.7%), pruritus (80%), erythema (75.2%), plaque formation (72.4%), and skin dryness (64.8%). Moreover, 29.5% of patients presented with a burning sensation, while pain or tenderness was observed in 17.1% of cases. The trunk was the most affected body part (68.6%), followed by the lower limbs (65.7%), upper limbs (58.1%), and scalp (51.4%). In addition, elbows and knees were affected in 45.7% and 43.8% of patients, respectively, while the back, face, palms/soles, and genital area were involved in 40%, 22.9%, 16.2%, and 5.7%, respectively. According to the PGA, most patients presented with moderate psoriasis (63.8%), while 19% had severe and 17.1% had mild disease.

Table II
Clinical characteristics, affected body areas, and disease severity among patients with psoriasis (*n*=105).

Characteristics	n (%)
Clinical symptoms	
Scaling	91 (86.7)
Pruritus	84 (80.0)
Erythema	79 (75.2)
Plaque formation	76 (72.4)
Skin dryness	68 (64.8)
Burning sensation	31 (29.5)
Pain/tenderness	18 (17.1)
Affected body areas	
Trunk	72 (68.6)
Lower limbs	69 (65.7)
Upper limbs	61 (58.1)
Scalp	54 (51.4)
Elbows	48 (45.7)
Knees	46 (43.8)
Back	42 (40.0)
Face	24 (22.9)

Palms/soles	17 (16.2)
Genital area	6 (5.7)
Disease severity (PGA)	
Mild	18 (17.1)
Moderate	67 (63.8)
Severe	20 (19.0)

Multiple responses were permitted; therefore, percentages do not sum to 100%.

Table III presents the progressive improvements in all the measured clinical indicators throughout the 12 weeks of treatment with tapinarof. The mean PASI score declined from 14.2 ± 5.8 at baseline to 11.0 ± 4.9 at week 4, 7.8 ± 4.1 at week 8, and 5.2 ± 3.5 at week 12. In turn, the mean involvement of the BSA was reduced from 18.6 ± 8.7% to 7.1 ± 5.0%, while the mean PGA score decreased from 3.1 ± 0.7 to 1.8 ± 0.6. The mean pruritus scores were also found to progressively decline from 6.2 ± 2.1 at baseline to 2.5 ± 1.4 at week 12. The noted changes were all statistically significant (p<0.001).

Table III
Changes in PASI, BSA, PGA and pruritus scores during treatment (*n*=105).

Outcome	Baseline Mean ± SD	Week 4	Week 8	Week 12	P-value
PASI, score	14.2 ± 5.8	11.0 ± 4.9	7.8 ± 4.1	5.2 ± 3.5	<0.001
BSA (%)	18.6 ± 8.7	14.5 ± 7.2	10.2 ± 6.1	7.1 ± 5.0	<0.001
PGA score	3.1 ± 0.7	2.7 ± 0.7	2.2 ± 0.7	1.8 ± 0.6	<0.001
Pruritus score	6.2 ± 2.1	4.8 ± 1.9	3.4 ± 1.6	2.5 ± 1.4	<0.001

Table IV shows the proportion of patients who had achieved clinically meaningful PASI responses increased progressively throughout treatment. The number of patients who had achieved PASI50 increased from 14 (13.3%) patients at week 4 to 39 (37.1%) patients at week 8 and 67 (63.8%) patients at week 12. Similarly, the number of patients who had achieved PASI75 increased from 3 (2.9%), 17 (16.2%), and 30 (28.6%) patients at weeks 4, 8, and 12, respectively. Finally, the number of patients who had achieved PASI90 increased from 1 (1.0%) patient at week 4 to 7 (6.7%) patients at week 8 and 15 (14.3%) patients at week 12. Thus, the results show that the treatment response improved progressively over the 12-week treatment period, with the greatest proportions of patients achieving PASI50, PASI75, and PASI90 at week 12.

Table IV
Proportion of patients achieving PASI50, PASI75, and PASI90 during 12 weeks of tapinarof treatment (*n*=105).

PASI response	Week 4, n (%)	Week 8, n (%)	Week 12, n (%)
PASI50 (≥50% improvement)	14 (13.3)	39 (37.1)	67 (63.8)
PASI75 (≥75% improvement)	3 (2.9)	17 (16.2)	30 (28.6)
PASI90 (≥90% improvement)	1 (1.0)	7 (6.7)	15 (14.3)

Note: PASI response categories are cumulative; patients achieving PASI75 or PASI90 are also included among those achieving PASI50.

Figure I present the adverse events that occurred during a 12-week tapinarof treatment. The majority of participants or 69 (65.7 %) did not experience any adverse events, whereas 36 (34.3 %) of them suffered from at least one adverse event. The most frequent adverse event was erythema that occurred in 11.4 % of participants, followed by pruritus affecting 8.6 percent of patients. In addition, 5.7 % of participants experienced burning or stinging, 3.8% had folliculitis, 2.9% presented with dryness or scaling, and 1.9% of patients suffered from other adverse events. Overall, it is possible to conclude that treatment was generally well-tolerated within a 12-week treatment period.

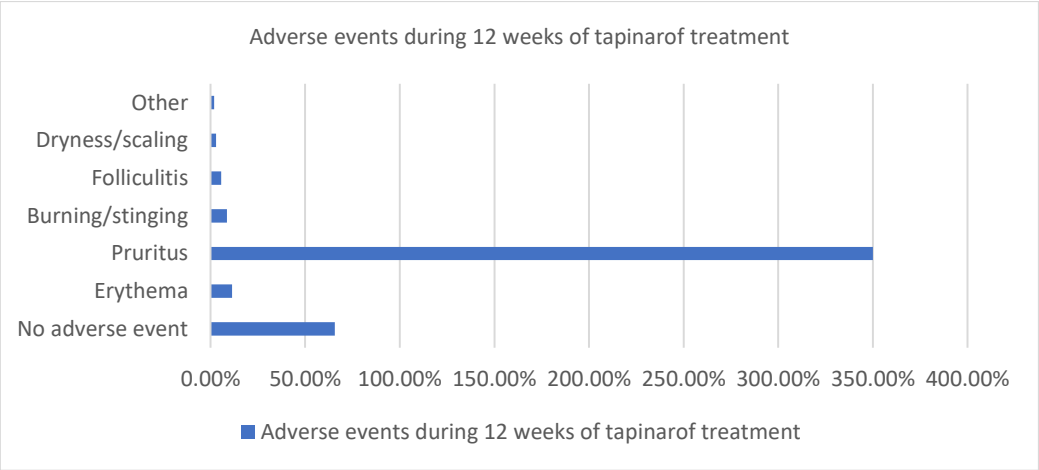


Figure 1 Adverse events during 12 weeks of tapinarof treatment (*n*=105).

Table V presents an association between disease severity at baseline and achievement of PASI75 after 12 weeks of treatment with tapinarof (p<0.001). PASI75 was achieved by 10 (55.6%) patients with mild disease, compared with 18 (26.9%) patients with

moderate disease and 2 (10.0%) patients with severe disease. Overall, 30 (28.6%) patients achieved PASI75, while 75 (71.4%) did not. The proportion of patients who achieved PASI75 declined with increasing baseline disease severity, suggesting that patients with less severe baseline disease were more likely to achieve PASI75.

Table V
Association between baseline disease severity and PASI75 response after 12 weeks of tapinarof treatment (*n*=105).

Baseline disease severity (PGA)	PASI75 achieved, n (%)	PASI75 not achieved, n (%)	Total, n (%)	P-value
Mild	10 (55.6)	8 (44.4)	18 (100.0)	
Moderate	18 (26.9)	49 (73.1)	67 (100.0)	
Severe	2 (10.0)	18 (90.0)	20 (100.0)	
Total	30 (28.6)	75 (71.4)	105 (100.0)	<0.001

DISCUSSION

In the present study, psoriasis was more common among males, with the largest proportion of participants aged 31–40 years. Most patients had moderate disease according to PGA, and scaling and pruritus were the predominant clinical manifestations. The high prevalence of pruritus is consistent with previous findings in Bangladeshi patients with psoriasis, highlighting its importance as a frequent and bothersome symptom of the disease [11]. The involvement of multiple body sites, particularly the trunk, lower limbs, upper limbs, and scalp, further reflects the extensive clinical burden among the study participants.

Treatment with tapinarof 1% cream resulted in significant and progressive improvement in disease severity over 12 weeks. The mean PASI score decreased from 14.2 ± 5.8 at baseline to 5.2 ± 3.5 at week 12, while BSA decreased from 18.6 ± 8.7% to 7.1 ± 5.0%. Significant reductions were also observed in PGA and pruritus scores (all $p<0.001$). These findings are consistent with phase 3 clinical trials demonstrating significant improvements in psoriasis severity following treatment with tapinarof cream [2,5]. The progressive reduction in disease measures throughout the treatment period suggests that continued use may provide increasing clinical benefit.

The proportion of patients achieving clinically meaningful PASI responses also increased with treatment duration. At week 12, PASI50, PASI75, and PASI90 were achieved by 63.8%, 28.6%, and 14.3% of patients, respectively. The improvement in pruritus was particularly notable, with the mean score decreasing from 6.2 ± 2.1 at baseline to 2.5 ± 1.4 at week 12. This finding supports previous evidence showing that tapinarof can produce meaningful and relatively rapid improvement in psoriasis-associated itch [12]. The observed efficacy is also comparable with real-world evidence from Bangladesh, which reported favorable effectiveness and safety of tapinarof 1% cream in routine clinical practice [13].

Baseline disease severity was significantly associated with PASI75 achievement at week 12 ($p<0.001$). Patients with mild disease had a higher PASI75 response rate than those with moderate or severe disease, suggesting that less severe disease may respond more readily to topical treatment. Nevertheless, meaningful responses were observed across all severity categories. Regarding safety, 65.7% of participants experienced no adverse events, while the reported events were mainly mild and included erythema, pruritus, burning or stinging, folliculitis, and dryness or scaling. This favorable tolerability profile is consistent with longer-term evidence supporting the sustained safety of tapinarof [4]. Overall, the present findings indicate that tapinarof 1% cream provides progressive improvement in psoriasis severity and pruritus, with clinically meaningful treatment responses and good short-term tolerability.

CONCLUSION

Topical tapinarof demonstrated significant and progressive improvement in disease severity over 12 weeks, with reductions in PASI, BSA, PGA, and pruritus scores. Clinically meaningful PASI responses increased throughout the treatment period, while treatment-related adverse events were generally mild and infrequent. The findings suggest that tapinarof is an effective and well-tolerated non-steroidal topical treatment for psoriasis and may represent a useful therapeutic option in routine clinical practice. Further studies with larger sample sizes and longer follow-up are warranted to confirm its long-term effectiveness and safety in the Bangladeshi population.

REFERENCES

1. Bissonnette MR, Gold ML, Tallman PA, Armstrong MA. Tapinarof in the treatment of psoriasis: A review of the unique mechanism of action of a novel therapeutic aryl hydrocarbon receptor–modulating agent. Journal of the American Academy of Dermatology. 2021 Apr 1;84(4):1059-67.
2. Lebwohl MG, Stein Gold L, Strober B, Papp KA, Armstrong AW, Bagel J, Kircik L, Ehst B, Hong HC, Soung J, Fromowitz J. Phase 3 trials of tapinarof cream for plaque psoriasis. New England Journal of Medicine. 2021 Dec 9;385(24):2219-29.
3. Nogueira S, Rodrigues MA, Vender R, Torres T. Tapinarof for the treatment of psoriasis. Dermatologic Therapy. 2022 Dec;35(12):e15931.
4. Strober B, Gold LS, Bissonnette R, Armstrong AW, Kircik L, Tyring SK, Piscitelli SC, Brown PM, Rubenstein DS, Tallman AM, Lebwohl MG. One-year safety and efficacy of tapinarof cream for the treatment of plaque psoriasis: results from the PSOARING 3 trial. Journal of the American Academy of Dermatology. 2022 Oct 1;87(4):800-6.
5. Igarashi A, Tsuji G, Fukasawa S, Murata R, Yamane S. Tapinarof cream for the treatment of plaque psoriasis: Efficacy and safety results from 2 Japanese phase 3 trials. The Journal of Dermatology. 2024 Oct;51(10):1269-78.
6. Robbins K, Bissonnette R, Maeda-Chubachi T, Ye L, Peppers J, Gallagher K, Kraus JE. Phase 2, randomized dose-finding study of tapinarof (GSK2894512 cream) for the treatment of plaque psoriasis. Journal of the American Academy of Dermatology. 2019 Mar 1;80(3):714-21.
7. Bissonnette R, Saint-Cyr Proulx E, Jack C, Maari C. Tapinarof for psoriasis and atopic dermatitis: 15 years of clinical research. Journal of the European Academy of Dermatology and Venereology. 2023 Jun;37(6):1168-74.
8. Gold ML, Bhatia MN, Tallman PA. A phase 2b, randomized clinical trial of tapinarof cream for the treatment of plaque psoriasis: secondary efficacy and patient-reported outcomes. Journal of the American Academy of Dermatology. 2021 Mar 1;84(3):624-31.
9. Lé AM, Torres T. New topical therapies for psoriasis. American Journal of Clinical Dermatology. 2022 Jan;23(1):13-24.
10. Armstrong AW, McConaha JL. Tapinarof cream 1% once daily for the treatment of adults with mild to severe plaque psoriasis: A novel topical therapy targeting the aryl hydrocarbon receptor. Journal of managed care & specialty pharmacy. 2023 Dec;29(12-a Suppl):S1-4.
11. Mowla MR, Alam MJ. P65 Clinical characteristics of pruritus in Bangladeshi psoriasis patients. Br J Dermatol. 2024;191(Suppl 3):ljae360.095. doi:10.1093/bjd/ljae360.095.
12. Kircik L, Zirwas M, Kwatra SG, Lewitt GM, Glover H, Chao T, et al. Rapid improvements in itch with tapinarof cream 1% once daily in two phase 3 trials in adults with mild to severe plaque psoriasis. Dermatol Ther (Heidelb). 2024;14(1):201-211. doi:10.1007/s13555-023-01068-x.
13. Huq S, Noor T, Chowdhury AH, Khan MAL, Asma AN, Malabeka S, et al. Real-world effectiveness and safety of tapinarof 1% cream in psoriasis: an observational study from Bangladesh. Cureus. 2026;18(2):e103183. doi:10.7759/cureus.103183.